United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 3, 1998 Decided December 29, 1998

No. 98-5334

Purepac Pharmaceutical Company,

Appellant

v.

Michael A. Friedman, M.D.,

Acting Commissioner of Food and Drugs,

Food and Drug Administration,

Appellee

Consolidated with

Nos. 98-5335 & 98-5337

Appeals from the United States District Court

for the District of Columbia

(98cv01780)

Robert A. Dormer argued the cause for appellants. With him on the joint briefs were James R. Phelps, Douglas B. Farquhar, David M. Malone, John F. Cooney, John R. Fleder, David F. Weeda and Arthur Y. Tsien. Brett T. Schwemer entered an appearance.

Howard S. Scher, Attorney, U.S. Department of Justice, argued the cause for the federal appellee. On the brief were Frank W. Hunger, Assistant Attorney General, Wilma A. Lewis, U.S. Attorney, Douglas N. Letter, Appellate Litigation Counsel, U.S. Department of Justice, and Jeffrica Jenkins Lee, Attorney.

James D. Miller argued the cause for intervenors-appellees Torpharm, A Division of Apotex, Inc., et al. With him on the joint brief were Eugene M. Pfeifer and Donald O. Beers.

Before: Randolph, Rogers, and Tatel, Circuit Judges.

Opinion for the Court filed by Circuit Judge Randolph.

Randolph, Circuit Judge: "The active ingredients in most prescription drugs constitute less than 10% of the product; inactive 'excipients' (such as coatings, binders, and capsules) constitute the rest. The term 'generic drug' is used to describe a product that contains the same active ingredients but not necessarily the same excipients as a so-called 'pioneer drug' that is marketed under a brand name." United States v. Generix Drug Corp., 460 U.S. 453, 454-55 (1983). New drugs, including new generic drugs, may not be marketed without the Food and Drug Administration's approval. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, revised the procedures for obtaining the FDA's approval. One of the provisions in the "Hatch-Waxman Amendments," as this Act is known, conferred on the first generic drug applicant a 180-day period during which it would be free of competition from generic applicants who file later. The FDA implemented this provision through a regulation. In Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998), we sustained a district court injunction against the FDA's enforcement of one of the regulation's requirements, finding it inconsistent with the statute. In response to Mova, the FDA revised its

system for granting the 180-day exclusivity period. The questions in this case concern the validity of the revision.

I

In July 1998, the FDA tentatively approved Purepac Pharmaceutical Company's application to market the generic drug ticlopidine hydrochloride, marketed by other companies under the brand-name "Ticlid."1 Although Purepac's application has become ready for final approval, the FDA is withholding action. Purepac must, the FDA insists, wait until the first ticlopidine applicant--Torpharm, a division of Apotex, Inc.--markets its product for 180 days. At the time of this writing, it is not certain when these 180 days will start running. The FDA has not yet finally approved Torpharm's application.

With matters thus at a standstill, Purepac decided to take legal action. It sued for an injunction and a declaratory judgment, challenging the validity of the FDA's post-Mova revision and claiming that Torpharm was not entitled to the 180-day exclusivity period because it had not been sued for patent infringement (a claim we will explain later in this opinion). Other companies intervened on Purepac's side; Torpharm and the companies who market the brand-name drug intervened as defendants.2 The district court denied Purepac's motion for a preliminary injunction and this appeal followed.

II

Under the Hatch-Waxman Amendments, an applicant seeking to market a new drug--that is, a "pioneer applicant"--must file a "New Drug Application." See 21 U.S.C. s 355(a). Among other things, the application must include full reports of investigations of the drug's safety and effectiveness. See 21 U.S.C. s 355(b)(1). An applicant seeking to market a generic drug may submit an "Abbreviated New Drug Application." As the name suggests, an abbreviated application is less demanding than a pioneer application; it may, for instance, rely on the safety and effectiveness studies submitted by the pioneer applicant. See 21 U.S.C. s 355(j)(2)(A)(i)-(v); Mead Johnson Pharm. Group v. Bowen, 838 F.2d 1332, 1333 (D.C. Cir. 1988). An abbreviated application also must include a certification that, for each of the patents applicable to the pioneer drug, the proposed generic drug would not infringe the patent because (I) the patent information has not been filed; (II) the patent has expired; (III) the patent will expire on a stated date; or (IV) the patent is invalid or will not be infringed by the manufacture, use or sale of the drug for which the abbreviated application

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1 Ticlid is widely prescribed for patients who have a high risk of thrombotic strokes and who cannot tolerate aspirin.

2 Invamed, Inc. and Teva Pharmaceuticals U.S.A., Inc. intervened as plaintiffs; Hoffman-LaRoche Inc. and Syntex (U.S.A.) Inc, in addition to Torpharm, intervened as defendants.

applicant seeks approval. See 21 U.S.C. s 355(j)(2)(A)(vii)(I)-(IV).

Our concern is with IV, the method Torpharm and then Purepac used. In a paragraph IV certification, the generic applicant must give notice to the owner of the patent, and to the holder of the approved application for the drug covered by the patent. See 21 U.S.C. s 355(j)(2)(B)(i). FDA approval of the abbreviated application may be made "effective immediately," unless a patent infringement suit is brought against the applicant within forty-five days from the date the patent owner or application holder receives notice of the paragraph IV certification. See 21 U.S.C. s 355(j)(5)(B)(iii).

No one brought a patent infringement suit against Torpharm (or Purepac) and it is therefore unnecessary to describe the provisions dealing with the various contingencies of such a lawsuit. The section directly in dispute--the section conferring the 180-day period of exclusivity--reads as follows:

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing3 such a certification, the application shall be made effective not earlier than one hundred and eighty days after-
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> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
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> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
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> whichever is earlier.

21 U.S.C. s 355(j)(5)(B)(iv), as amended by Pub. L. No. 105-115, 111 Stat. 2296 (1997).

The FDA's original regulation implementing this section, promulgated in 1994, provided:

> If an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable or would not be infringed and the applicant submitting the first appli-

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3 This should probably read "containing." See Mova Pharm. Corp., 140 F.3d at 1064 n.3.

> cation has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice submitted under s 314.95, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier:
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> (i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or
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> (ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.

59 Fed. Reg. 50,338, 50,367 (1994) (emphasis added). The italicized language embodied what the parties and our Mova opinion call the "successful defense" requirement: the first generic applicant was entitled to the 180-day exclusivity period only after it had successfully defended a patent infringement suit.

Mova held that this portion of the regulation was "inconsistent with the statutory text and structure." 140 F.3d at 1076.4 As the court read the statute, it provided that a later generic applicant could not start marketing its product for 180 days after either commercial marketing by the first applicant, or a court decision declaring the patent invalid or not infringed. Id. at 1069. The FDA's successful defense requirement read the commercial marketing "trigger" out of the statute. As a result, first applicants who were not sued could never receive the benefit of the exclusivity period. Id.

After Mova, the FDA issued a "Guidance to Industry" announcing its intention to "formally" remove the successful defense requirement from the regulation and to conduct a rulemaking proceeding to issue new regulations under s 355(j)(5)(B)(iv). In the meantime, the FDA said it would follow the statute as Mova interpreted it. That is, the agency would inform "the first applicant to submit a substantially complete" abbreviated application, "with a paragraph IV certification," that the applicant was eligible for 180 days of market exclusivity even though it had not been sued for patent infringement. The FDA added that it expected first applicants to begin marketing their product "promptly upon approval."

In November 1998, while this case was pending, the FDA published an interim rule in the Federal Register amending its regulation to eliminate the successful defense requirement. The interim rule accomplished this by deleting from the regulation the following language, italicized above (21 C.F.R. s 314.107(c)(1)): "and the applicant submitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's

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4 The Fourth Circuit, in an unpublished decision, reached the same result, Granutec, Inc. v. Shalala, 1998 U.S.App. LEXIS 6685, at * 19 (4th Cir. Apr. 3, 1998).

receipt of notice submitted under s 314.95."5 See 63 Fed. Reg. 59,710, 59,712 (1998).

III

We come at last to Purepac's legal arguments. In essence, Purepac maintains that the regulation containing the successful defense requirement did not entitle Torpharm to the 180-day exclusivity period because Torpharm had not been sued for patent infringement. As Purepac sees it, even after Mova the FDA still had to require, as a condition for exclusivity, that the first generic applicant be sued for patent infringement, although the FDA could no longer insist that the applicant defend the suit successfully.

The FDA's Guidance for Industry embraced a different interpretation of Mova and of the severability of the regulation: under the Guidance, a first applicant like Torpharm did not have to be sued in order to be entitled to the exclusivity period. Purepac opposed the Guidance on a procedural ground, claiming that the FDA had gone beyond the mandate of Mova, and thereby effectively amended the regulation, something agencies may do only through notice and comment rulemaking, or through an interim rule. The FDA's promulgation of an interim rule duplicating the Guidance puts an end to Purepac's arguments in this regard.

In apparent anticipation of the FDA's issuing an interim rule (as the Guidance suggested it would), Purepac's brief also contended that the agency could not validly use this procedure because it would be unable to show "good cause" under 5 U.S.C. s 553(b)(B), a necessary condition for dispensing with pre-promulgation notice and comment. See Mid-Tex Elec. Co-op., Inc. v. FERC, 822 F.2d 1123, 1131-33 (D.C. Cir. 1987). The basis for this contention is basically the same

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5 The interim rule also amended 21 C.F.R. s 314.107(c)(4) by deleting the phrase "if sued for patent infringement." See 63 Fed. Reg. at 59,712. The original regulation had provided that the first applicant should notify the FDA of the date that it commenced commercial marketing, "if sued for patent infringement." See 59 Fed. Reg. at 50,368.

as Purepac's procedural challenge to the Guidance: Mova did not strike down the regulation's requirement that the first applicant must defend a lawsuit before being eligible for the 180-day exclusivity period; the only portion of the regulation Mova rendered unenforceable was the requirement that the applicant "successfully" defend the lawsuit; and because this so-called "lawsuit" requirement remained untouched by Mova, the FDA would have no grounds for claiming that it faced some pressing need, some good cause, to dispense with notice and comment before promulgating an amendment to the regulation. Purepac also advanced the same line of reasoning to support its position that the FDA's response to Mova was irrational and inconsistent with s 355(j)(5)(B)(iv).

We see the FDA's revised system for granting exclusivity as consistent with the statute and with our Mova decision. Section 355(j)(5)(B)(iv) does not, on its face, require the first applicant to be sued in order to benefit from market exclusivity. It provides, as we said in Mova, that the 180-day exclusivity period for the first applicant begins running upon the occurrence of one of two events, whichever is earlier--commercial marketing by the first applicant, or a court decision in favor of the applicant. 140 F.3d at 1069. The second condition obviously presupposes a lawsuit. The first does not. The words of the statute provide no reason to think, as Purepac must, that the only "commercial marketing" contemplated in s 355(j)(5)(B)(iv) is marketing that takes place while the first applicant is defending a lawsuit or after the lawsuit has concluded. The regulation, as it now stands, is fully consistent with the statute. By removing the language embodying the successful defense requirement, the FDA eliminated a significant difference between its regulation and s 355(j)(5)(B)(iv).

Agencies occasionally promulgate a regulation merely duplicating the underlying statute. As matters stand after the FDA's revisions, its regulation is of that type. There is nothing irrational in the FDA's giving first applicants the 180-day exclusivity period even if they have not been sued. On its face, the statute does the same. Seen in this light,

Purepac's real objection is to the words Congress used, not the FDA's revision of its regulation.

Purepac points out that in the preamble to the final rule containing the successful defense requirement, the FDA stated that the statute--s 355(j)(5)(B)(iv)--"can be applied straightforwardly only when the applicant who seeks the 180-day period of exclusive marketing has been involved in a patent infringement lawsuit." 59 Fed. Reg. at 50,353. Whether this and other remarks in the preamble were intended to convey the idea that the statute should be read to require a lawsuit against the first applicant, although not a successful defense of the lawsuit, is uncertain and, in any event, beside the point. The FDA's current position is that, as a temporary measure pending a rulemaking proceeding, it will not infer requirements for exclusivity that are not in the statutory text. Its explanation for this position is more than adequate: the decision in Mova forced it to go back to the drawing board.

Purepac also offers a policy reason for reading a lawsuit requirement into s 355(j)(5)(B)(iv). If a first applicant is never sued for patent infringement, it is possible that neither of two "triggers" for the running of the 180 days of market exclusivity--commercial marketing or a judicial decision--would ever occur. Without a lawsuit there would be no judicial decision. If the applicant never begins marketing its product, the 180 days would never run and all later generic applicants would be barred from bringing their products to market. Purepac's point is hardly new. Mova discussed it at some length, 140 F.3d at 1067, said in dictum that a lawsuit requirement "would have corrected the problem," id. at 1071,6

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6 It is not clear that the "problem" would be entirely solved. Suppose, as Purepac proposes, only the word "successfully" were eliminated from the regulation, thus retaining as a condition to receiving exclusivity that the first applicant "has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice." Suppose further that a first applicant is sued but that the suit does not result in a judicial decision finding the patent not infringed or invalid, so that the

and then cautioned that "Congress may have intended to reward the first ... applicant for his enterprise whether or not he is later sued," thus suggesting that a lawsuit requirement might be inconsistent with congressional intent. See id. at 1071 n.11. For this reason, Mova described a narrower answer to the problem: for first applicants who are not sued, they must bring their products to market within a prescribed period in order to benefit from exclusivity. See id. There is some indication that the FDA will consider this alternative in the rulemaking promised in its Guidance, or in response to comments on its interim rule.7 That is the proper time and setting for Purepac to repeat its point and to offer its solution. In the meantime, the FDA has implemented an interim measure, basically duplicating the statute. The FDA's action, pursuant to which it is withholding final ap-

proval of Purepac's generic application pending Torpharm's commercial marketing, is not irrational, it is not inconsistent with s 355(j)(5)(B)(iv) and it is not contrary to the mandate in Mova.

The district court's judgment denying the motion for a preliminary injunction is therefore affirmed.

So ordered.

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judicial decision trigger in s 355(j)(5)(B)(iv) is not activated. This could happen if, for instance, the suit is dropped or settled. In those events, only commercial marketing could trigger the running of the 180-day period. And the same problem Purepac identifies would exist if the first applicant fails to market its product.

7 The Guidance stated that first applicants who are not sued will receive a letter from the FDA telling them that they will nevertheless receive the benefit of exclusivity, but warning that the agency "expects that you will begin commercial marketing of your product promptly upon approval."